DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 20 2009

Re: Soliris
Docket No.: FDA-2007-E-0166

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,355,245, filed by Alexion Pharmaceuticals, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Soliris (eculizumab), the human biological product claimed by the patent.

The total length of the regulatory review period for Soliris (eculizumab) is 1,360 days. Of this time, 1,177 days occurred during the testing phase and 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 27, 2003.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 27, 2003.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: September 15, 2006.

   FDA has verified the applicant's claim that the biologics license application (BLA) for Soliris (eculizumab) (BLA 125166/0) was initially submitted on September 15, 2006.

3. The date the application was approved: March 16, 2007.

   FDA has verified the applicant's claim that BLA 125166/0 was approved on March 16, 2007.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Stephen A. Saxe, Ph.D.
Alexion Pharmaceuticals, Inc.
Intellectual Property
352 Knotter Drive
Cheshire, CT 06410